UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

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In Re:

Bair Hugger Forced Air Warming

Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

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DEPOSITION OF TIMOTHY A. ULATOWSKI

VOLUME I, PAGES 1 - 414

JULY 7, 2017

(The following is the deposition of TIMOTHY A. ULATOWSKI, taken pursuant to Notice of Taking Deposition, via videotape, at the Renaissance Arlington Capital View Hotel, 2800 Potomac Avenue, Arlington, Virginia, commencing at approximately 9:02 o'clock a.m., July 7, 2017.)

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09:07:40 Q. Okay. And then you were also a director in
09:07:40 the Center for Devices and Radiological Health?
09:07:43 A. I was -- I was one of half a dozen
09:07:45 directors, office directors.
09:07:46 Q. Right. A director?
09:07:47 A. I was a director.
09:07:48 Q. Okay. After leaving the FDA, you started
09:07:52 testifying in numerous lawsuits relating to medical
09:07:56 devices.
09:07:57 A. "Numerous" meaning --
09:07:59 Q. More than one.
09:08:00 A. Yes.
09:08:00 Q. Okay. In fact, a significant source of your
09:08:04 income, to come to courtrooms and rooms like this and
09:08:09 give testimony that medical devices which are alleged
09:08:12 to be unsafe are in fact safe.
09:08:14 MS. EATON: Object to the form of the
09:08:15 question.
09:08:16 A. Well the -- the aspects of the case are --
09:08:19 are unique in every instance in regard to what are the
09:08:21 issues at hand, and I testify for -- for defendants
09:08:25 and plaintiffs.
09:08:26 Q. Well when you're on the plaintiff's side,
09:08:27 it's a medical device company though; right?
09:08:29 A. Not always, no.

09:22:54 "here" meaning in that case -- "to testify as an
09:22:56 expert in any sort of medical area," and I said, "No,
09:22:59 I am not."
09:23:00 Q. Okay.
09:23:00 A. Well that was that case under those
09:23:03 conditions, under that -- that set of evidence
09:23:06 with -- given my opinions that I expressed in that
09:23:10 case. Today, here we are in July of -- of 2017,
09:23:15 different set of documents, different set of
09:23:16 experiences. But I have my opinions expressed in my
09:23:19 report.
09:23:19 Q. Okay. So as opposed to in I-Flow, today in
09:23:23 this case with these documents, with your opinions
09:23:25 today, are you giving medical opinions?
09:23:28 A. I don't have any medical opinions in my
09:23:31 report.
09:23:32 Q. So that's a no; correct?
09:23:34 A. That's --
09:23:35 It's as what I stated.
09:23:36 Q. I don't -- I don't understand because I
09:23:38 asked you if you were giving medical opinions here
09:23:41 today in this room -- you, individual, Ulatowski --
09:23:44 and you told me about your report, which leads me to
09:23:47 suggest that there may be some disconnect between what
09:23:50 your report contains and what you plan to testify

09:24:57 today? Are you going to be giving any opinions like
09:25:01 that?
09:25:01 A. I -- none of my --
09:25:04 All my opinions are regulatory-focused. I
09:25:08 don't provide comment on any particular engineering
09:25:15 test methodologies, except in Dr. David I provided an
09:25:19 overview comment of his approach in regard to his
09:25:22 report. But other than that, certainly I think my
09:25:28 report discusses aspects of disinfection of medical
09:25:34 equipment which has a methodology to it, so it -- it's
09:25:37 kind of -- it depends as to what I'm asked and what's
09:25:43 reflected in my report.
09:25:44 Q. So your expertise changes from the type of
09:25:47 questions you're asked is what you're saying.
09:25:48 MS. EATON: Object to the form of the
09:25:49 question.
09:25:50 A. No. I have expertise in -- in areas that
09:25:53 questions may provoke an answer that rely upon my
09:25:57 expertise in those areas.
09:25:58 Q. Okay. For instance, one of the things that
09:26:00 is involved in this case you understand is a surgery;
09:26:02 right?
09:26:02 A. Is -- is surgery.
09:26:04 Q. Correct. Surgeries are involved in this
09:26:06 case.

09:26:06 A. Yes.

09:26:07 Q. Okay. You don't hold yourself out as an
09:26:08 expert in any kind of surgical areas such as
09:26:12 orthopedic surgery.

09:26:13 A. No.

09:26:13 Q. You're not going to be giving the jury an
09:26:16 opinion within a reasonable degree of medical
09:26:20 certainty that there is valid scientific evidence of
09:26:22 probable health benefits from the use of the Bair
09:26:25 Hugger in orthopedic surgeries.

09:26:36 A. Well I -- I allude to that in my report in
09:26:41 regard to benefit and risk, so inasmuch as my report
09:26:46 touches upon benefit aspects and -- and risk, which is
09:26:50 reflected in clinical studies, published data, my
09:26:55 report is what it is.

09:26:56 Q. Well right. And that report does not
09:26:58 contain an opinion to a reasonable degree of medical
09:27:02 certainty that there is valid scientific evidence of a
09:27:05 probable health benefit from the use of the Bair
09:27:08 Hugger in orthopedic surgeries.

09:27:11 A. In orthopedic surgeries. Well I guess I
09:27:13 have to look at my report because I do discuss valid
09:27:16 scientific evidence and I do discuss the relationship
09:27:21 with certain data submitted to FDA as consisting of
09:27:25 valid scientific evidence. So again, it's a -- it's

09:27:28 the question, it's the specifics that you may ask.
09:27:30 Q. Well let's dive into that. In terms of you
09:27:33 giving opinions that there is, within a reasonable
09:27:35 degree of medical certainty, valid scientific evidence
09:27:38 of probable health benefits from the use of the Bair
09:27:40 Hugger in orthopedic surgeries, what is that
09:27:43 scientific evidence?
09:27:43 A. Well it wouldn't be -- let me clarify. It
09:27:46 wouldn't be --
09:27:48 I think in my report as I characterized it,
09:27:51 again, from a regulatory point of view, it was valid
09:27:54 scientif -- scientific evidence applied to the Bair
09:27:58 Hugger in regard to its regulatory significance, not
09:28:03 medical significance.
09:28:03 Q. Okay. So in other words, you may be giving
09:28:06 us opinions about whether or not the defendant
09:28:10 complied with the regulatory scheme that you oversaw
09:28:12 during your many years at the FDA, but at the same
09:28:15 time you will not be giving an opinion, a medical
09:28:18 opinion, about the benefits of a Bair Hugger in
09:28:20 orthopedic surgery. Is that fair?
09:28:23 A. Generally, no.
09:28:24 Q. Okay. Just because that may be a little --
09:28:28 on the record, are you -- are you disagreeing and
09:28:31 saying you will be giving medical opinions on the

09:28:33 benefits of the Bair Hugger in orthopedic surgery or
09:28:35 you will not be giving those medical opinions?
09:28:37 A. I will not. But it depends on -- again, on
09:28:41 the question asked and whether it touches upon
09:28:43 expertise I may have.
09:28:44 Q. Okay. Well in terms of the question I just
09:28:46 asked and when I asked you for the scientific
09:28:50 evidence, do you have a medical opinion about the
09:28:52 benefits of the Bair Hugger in orthopedic surgeries?
09:28:57 A. No. I've refer -- referenced other groups
09:29:02 and persons who have commented on that as a basis for
09:29:06 certain opinions I have.
09:29:06 Q. And there are other experts in this case, I
09:29:08 assume you know from reading your reports, who have
09:29:11 given medical opinions and are giving medical opinions
09:29:14 on behalf of 3M; correct?
09:29:15 A. Yes, I know that.
09:29:16 Q. Okay. You would agree with me that in terms
09:29:19 of whether the Bair Hugger has medical benefit in an
09:29:22 orthopedic surgery, witnesses such as that are far
09:29:26 better addressed to answer that question than somebody
09:29:30 with your lack of medical training.
09:29:30 MS. EATON: Object to the form of that
09:29:32 question.
09:29:32 A. I would -- I would defer to other defendant

09:29:35 experts that have more direct experience in that
09:29:38 regard.
09:29:39 Q. Okay. By the same token, you will not be
09:29:43 giving the jury an opinion to a reasonable degree of
09:29:46 medical certainty about the degree of medical risk
09:29:47 from the use of the Bair Hugger in orthopedic
09:29:49 surgeries.
09:29:50 A. Medical risk?
09:29:52 Q. Correct.
09:29:53 A. I would defer to other defendant experts in
09:29:56 regard to that.
09:29:56 Q. You don't hold yourself out as an expert in
09:29:59 statistics or statistical analysis; correct?
09:30:01 A. No, I do not.
09:30:04 Q. Okay. Now before you accept any litigation
09:30:07 work, do you agree with me you have to make sure you
09:30:10 don't have any conflicts of interest relating to the
09:30:12 work?
09:30:12 A. That's correct.
09:30:13 Q. I'm wondering: Did you contact anybody at
09:30:17 the FDA, like an ethics officer, about your testimony
09:30:19 in this case?
09:30:20 A. I have.
09:30:20 Q. Okay. And can you tell me --
09:30:21 A. In this case?

09:39:54 that this product should not have cleared 510(k), both
09:39:58 as the Bair Hugger 500 and 750 series.
09:40:02 MS. EATON: Object to the form of the
09:40:02 question.
09:40:03 A. Well I don't think he comes out and says
09:40:06 that directly. I think he says the -- the process
09:40:08 was -- was troubling in one respect or another. Of
09:40:11 course I found otherwise, but -- but I -- I just -- I
09:40:17 just disagree with his perspective on the 510(k).
09:40:21 Q. Sure. We'll get to all of that.
09:40:23 A. Sure.
09:40:25 Q. All I'm trying to set up -- and I'm going to
09:40:26 use your word -- is you understand Dr. David is
09:40:28 critical in that he calls the regulatory history of
09:40:31 this product alarming; correct?
09:40:32 MS. EATON: Object to the form of the
09:40:33 question. That's not what he said.
09:40:34 A. Well I mean "troubling" was --
09:40:35 Q. "Troubling," I'm sorry, your word was
09:40:37 "troubling." Let's do it again, put it on the record
09:40:41 again.
09:40:41 You understand that Dr. David in his report
09:40:41 criticizes the regulatory process as troubling.
09:40:44 A. Yes.
09:40:45 Q. Okay. But in this case we don't have the

09:40:48 kind of conflict we were just talking about because
09:40:50 you were never involved in any kind of 510(k) approval
09:40:53 for this product; right?
09:40:54 A. Clearance for the product, no.
09:40:56 Q. And again, let me go ahead and make that
09:40:59 clear for the record. And please keep correcting me
09:41:02 if I use the wrong word today because eventually you
09:41:06 will probably drill it into my head. But in terms --
we don't --
09:41:08 In this case we don't have the same conflict
09:41:10 we had just been talking about where you may have a
09:41:12 plaintiff alleging something about 510(k) when you
09:41:15 were involved in it. In this case you had no
09:41:17 involvement, did -- made no approvals in 510(k);
09:41:19 correct?
09:41:20 A. 510(k) clearances, yes.
09:41:22 Q. 510(k) clearances.
09:41:23 A. Right.
09:41:24 Q. Okay. So the poten --
09:41:24 According to you, there is no potential
09:41:26 conflict because there is no approval letter from
09:41:31 Timothy Ulatowski regarding the Bair Hugger.
09:41:32 Or excuse me.
09:41:32 MS. EATON: Object to the form of the
09:41:33 question.

09:46:50 kind of action is that?
09:46:51 A. An advisory action.
09:46:52 Q. Okay. And -- and an advisory action is --
09:46:56 Those are actions that you had
09:46:57 responsibility at during what approximate time of your
09:47:00 tenure?
09:47:00 A. 2003 to 2011.
09:47:02 Q. Okay. During that entire period of that
09:47:04 space, you were involved in advising companies if they
09:47:09 were perhaps in violation or potential violation of
09:47:12 regulations.
09:47:13 A. Correct.
09:47:13 Q. Okay. One of the people that you made an
09:47:17 advisory action to is your current client.
09:47:22 A. Correct.
09:47:23 Q. That --
09:47:25 And that advisory letter concerned adverse
09:47:28 events.
09:47:29 A. Correct.
09:47:30 Q. Those adverse events, those were burns;
09:47:33 right?
09:47:33 A. That was associated, yes. Right.
09:47:36 Q. And there were burns that had not been
09:47:40 properly reported by the company.
09:47:41 A. There were reporting issues that were

observed.

Q. You're familiar with what I say when I say MDR?

A. Correct.

Q. Can you explain to the jury real quick what an MDR is.

A. Medical device report. It's a report made to FDA by manufacturers, by healthcare facilities, by importers related to deaths or serious injuries that -- or malfunctions that -- that may be related or associated with a medical device.

Q. That may be related; correct?

A. Correct.

Q. Okay. In other words, if a -- a manufacturer has information in its possession that a device is potentially involved in an adverse event, under certain circumstances that has to be reported.

A. If there's reasonable evidence to that fact, yes.

Q. Okay. In the case of your advisory letter, there were adverse events that legally should have been reported to the FDA but were not reported to the FDA by Arizant; correct?

A. As I recall, there were observations related to late reports or non-reports, yes. A few.

09:48:46 Q. You would agree with me that the bulk of
09:48:49 your opinions in this case focus on FDA regulations,
09:48:51 FDA procedures such as the 510(k) clearance process,
09:48:55 FDA communications, defendants' compliance with
09:49:00 regulatory duties, these are the general things you're
09:49:04 testifying about.
09:49:04 A. That's the bulk of it, although there's a --
09:49:08 a -- I'll call it a smattering of -- of expertise I --
09:49:13 I offer in regard to a particular area of expertise I
09:49:16 have in regard to disinfection, sterilization for
09:49:19 example.
09:49:19 Q. Okay. For my next series of questions I
09:49:22 want to limit us to the parts and opinions of your
09:49:24 report that deal with the 510(k) process. Okay?
09:49:28 A. Okay.
09:49:29 Q. From the way I understand it, 510(k) is a
09:49:32 determination by the FDA that a product being offered
09:49:36 in the application is substantially equivalent to a
09:49:40 previously-legally-marketed product.
09:49:42 A. That's correct.
09:49:43 Q. Okay.
09:49:43 A. That is also Class II and subject to legal
09:49:47 marketing, as you said.
09:49:49 Q. Okay.
09:49:49 A. For classification number.

09:49:51 Q. You would agree that your opinions in this
09:49:53 case both implicate the 510(k) clearance process in
09:49:56 general and with respect to Bair Hugger specifically.
09:49:59 A. Correct.
09:49:59 Q. Okay. You would also say that the 510(k)
09:50:05 process speaks to or relates to safety and efficacy.
09:50:10 A. Yes. It must.
09:50:11 Q. Okay. In fact, you have testified before
09:50:17 and I believe you'll be testifying today that 510(k)
09:50:19 clearance is a determination of safety and
09:50:21 effectiveness.
09:50:22 A. No, I am not.
09:50:23 Q. Okay. That's not going to be your opinion
09:50:25 today.
09:50:25 A. No.
09:50:26 Q. Okay. I notice your report provides a
09:50:31 narrative description of the FDA processes for
09:50:33 regulating medical devices; is that correct?
09:50:35 A. Correct.
09:50:36 Q. It has an overview of forced-air warming
09:50:40 devices generally?
09:50:41 A. Generally, yes.
09:50:42 Q. Okay. It has -- discusses a history of
09:50:45 Arizant's 510(k) submissions?
09:50:47 A. Right, to the degree that I could discover

09:50:49 that on FDA's website.

09:50:50 Q. Okay. Now all of those things we just

09:50:57 talked about, these opinions that you hold, you will

09:50:59 agree with me multiple federal courts have excluded

09:51:03 those opinions as improper.

09:51:04 MS. EATON: Object to the form of the

09:51:05 question.

09:51:05 A. No, that's incorrect.

09:51:07 Q. Okay. Do you remember in --

09:51:08 You remember the Bellew versus Ethicon case?

09:51:11 A. Well let me -- let me try and clarify what I

09:51:16 just said. I know that certain judges have excluded

09:51:21 testimony on 510(k)s simply because they -- they don't

09:51:25 want to talk about federal regulations and 510(k)s.

09:51:28 It's not me, it's not my report, it's just an overall

09:51:32 decision that we're not going to talk about this

09:51:35 topic.

09:51:36 Q. You don't believe that federal courts have

09:51:38 stated that you have stated the law incorrectly?

09:51:40 A. Well if you let me finish -- you jumped in.

09:51:44 The other half has been in a case people

09:51:49 have brought up, Medtronic/Lohr, for example, and the

09:51:54 Supreme Court's decision on PMAs, premarket approval

09:51:58 applications versus 510(k)s, although the fact is that

09:52:03 I've recognized the regulatory standard for PMAs

09:54:20 question.

09:54:20 A. I -- I don't recall that specific wording,

09:54:22 but that sounds like a legal approach.

09:54:27 Q. Today we're not going to have that kind of

09:54:30 opinion.

09:54:31 A. I'm not a lawyer. I'm not going to --

09:54:33 I haven't proposed my opinions in those

09:54:35 in -- in the framework of a -- of a -- of a

09:54:38 litigation -- legally-based litigation aspect.

09:54:42 Q. And therefore you're not going to be giving

09:54:44 an opinion about whether the design of the Bair Hugger

09:54:46 device was negligent or non-negligent.

09:54:54 A. Well I guess I have to understand the

09:54:56 parameters of the definition and what that entails.

09:55:00 You know, I understand that from a -- from a --

09:55:04 I understand at least that from a -- from a

09:55:06 legal position that there's -- one has to be very

09:55:10 careful in how one approaches the negligence and

09:55:12 defect in regard to how that is defined in a

09:55:16 particular state or particular MDL versus as FDA may

09:55:19 define safety and effectiveness and how that -- those

09:55:23 things differ.

09:55:23 Q. Okay. Similarly, likewise -- because you

09:55:26 brought up the term, it's going to be my next

09:55:29 question -- is about the concept of defect. And are

09:55:31 you going to be giving an opinion in this case that
09:55:33 the Bair Hugger is or is not defective?
09:55:36 A. I haven't rendered an opinion on that.
09:55:38 Q. Okay.
09:55:39 A. My position is, from a reg -- regulatory
09:55:42 perspective, were these products found substantially
09:55:45 equivalent or the basis for ---for those findings, so
09:55:51 on and so forth.
09:55:52 Q. Okay. We had talked a little bit earlier
09:56:00 about the 510(k) clearance process and about clearance
09:56:04 being granted when a product is found to be
09:56:06 substantially equivalent to a previously-legally-
09:56:09 marketed device. Do you remember that?
09:56:11 A. Yes.
09:56:11 Q. Okay. In terms of what "substantially
09:56:15 equivalent" means, you would agree that that means the
09:56:18 product has the same intended use and same
09:56:22 technological characteristics, or it may have
09:56:25 differences but those do not raise new questions of
09:56:28 safety or effectiveness.
09:56:29 A. Yes. That's how the statute and -- and --
09:56:32 is embedded in the regulations.
09:56:34 Q. Okay. You would also agree with me that the
09:56:36 510(k) process is a very liberal process in regards to
09:56:40 the uses of its products.

10:02:50 A. Right, yes. The IOM, yes.
10:02:52 Q. And then as soon as IO --
10:02:55 Like when the IOM came out is roughly
10:02:57 concurrent with when you left the agency.
10:03:00 A. When the report came out, yes.
10:03:01 Q. Correct. That report --
10:03:02 MS. EATON: Can I just clarify? You said
10:03:05 2001, and I think you meant 2011.
10:03:08 MR. BANKSTON: That is true.
10:03:09 THE WITNESS: Yeah. I let that go by.
10:03:09 MS. EATON: I just want that to be clear on
10:03:11 the record.
10:03:11 Q. Yeah. You left the agency in 2011.
10:03:14 A. '11, yes.
10:03:14 Q. That's when the IOM report was published.
10:03:17 A. It was thereabouts, yes.
10:03:19 Q. Okay. That IOM report states/finds that the
10:03:21 510(k) process was not designed to determine whether a
10:03:23 new device provides a reasonable assurance of safety.
10:03:29 A. Yeah. The -- the IOM --
10:03:32 There's only two real conclusions in the IOM
10:03:36 report, and one of them is the 510(k) process was not
10:03:39 designed to evaluate safety and effectiveness in
10:03:44 certain cases, but the fact of the matter is, as FDA
10:03:49 has implemented the process, it certainly had to

10:10:16 A. Yes.

10:10:16 Q. Okay. You'll agree -- and I have some language there I believe you'll see there on page 65 -- and you'll agree that the working group found that the Center for Devices and Radiological Health does not have an adequate mechanism to regularly assess the quality, the consistency, and the effectiveness of the 510(k) program. I'm assuming you were made aware of that.

10:10:40 A. Yeah. Let me just read it. I -- I recall it.

10:10:50 Yes, I understand this. I -- I think it's not quite accurate in that CDRH actually had gone through --

10:11:01 If you were there long enough -- you know, 37 years -- you would have been aware, and these -- I don't think these people have awareness of it, but FDA had -- had been through previous cycles of analysis of the 510(k) program, had undergone a -- an intensive evaluation of the 510(k) program and consistency in the 510(k) program and retrospective analysis of prior 510(k) decisions, one of them is called the Temple Report, and I think what this group was saying, we need to build in that sort of review process more frequently and more systematically than what we've

10:14:48 Q. Sure. I mean the FDA is rigorous about this. It values that support.

10:14:50

10:14:52 A. Correct.

10:14:52 Q. And one of those people would be Dr. Yadin David.

10:14:56

10:14:57 A. I comment on my understanding of his, based on his CV that he produced and my fading knowledge of my interaction with him, what his experience was.

10:15:00

10:15:05

10:15:08

10:15:08 Q. Uh-huh. He was a private-sector consultant that was engaged by the FDA.

10:15:10

10:15:13 MS. EATON: Object to the form of the question.

10:15:15

10:15:15 A. Well he attests to the fact that he's on the GMP committee. I don't think he attests to anything more.

10:15:20

10:15:22

10:15:22 Q. He's on several committees according to his CV; isn't he?

10:15:25

10:15:26 A. Not FDA committees --

10:15:27 Q. Okay.

10:15:28 A. -- is my understanding from his CV.

10:15:32 Q. Okay. You'll agree with me that it's the manufacturer, not the FDA, who is primarily responsible for the assurance of safety of medical devices.

10:15:34

10:15:37

10:15:39

10:15:45 A. Yes. The regulations are geared to the fact
10:15:47 that the manufacturer must follow regulations in order
10:15:52 to design and manufacture and monitor the devices,
10:15:56 with the surveillance and oversight of FDA.
10:15:58 Q. Right. The FDA can't monitor each and every
10:16:01 manufacturer and the marketing of each and every
10:16:04 product; can it?
10:16:04 A. No. That's why FDA prioritizes its
10:16:07 monitoring and its evaluation of devices.
10:16:20 Q. One of the opinions you give in your report
10:16:24 is that the FDA must consider issues of safety and
10:16:26 effectiveness when comparing any differences in
10:16:31 indications for use in claims. You'd agree with that?
10:16:33 A. Correct.
10:16:33 Q. Okay. And -- and I think, as we saw from
10:16:36 your I-Flow testimony, you'll agree that prior
10:16:38 clearances have just as much importance and effect as
10:16:41 current clearances.
10:16:42 MS. EATON: Object to the form of the
10:16:44 question.
10:16:44 A. Yes. They have an impact on assessing
10:16:47 indications and intended use.
10:16:48 Q. The prior clearances have just as much
10:16:54 importance as the current submission.
10:16:56 MS. EATON: Object to the form of the

know, FDA was certainly made aware at that point in time with the 505.

As far as the 500, I'm -- I'm recollecting the data submitted and I'm not sure if there was OR references in there as I recall.

Q. Okay. What about the 500 OR, do you know anything about that product?

A. Yeah. Variation of the 500 probably, yes.

Q. Okay. When the FDA became aware that the IFUs were being expanded to include OR usage, part of the job then of the FDA would be to determine if that expansion of IFUs presented any new questions of safety.

MS. EATON: Object --

A. Right.

MS. EATON: -- to the form of the question.

A. Yes. That would be an element for FDA to consider. And we know that in the 505 they actually considered the flip side, which was home use, as being potentially significant. So yes, FDA was analyzing the -- the -- the -- the possibilities for use of the product.

Q. Okay. What did the FDA do to determine that the Bair Hugger's expansion of use into the OR did not pose any new questions of safety?

10:27:37 A. Well we don't have available to us the
10:27:40 reviews by FDA, so we don't -- we cannot benefit from
10:27:46 that, but as a -- as a matter of policy and procedure,
10:27:49 FDA would be required to evaluate that, bring to -- to
10:27:53 bring to bear not only what's been submitted but also
10:27:56 any other information it may bring to bear in its
10:28:00 knowledge of patient warming devices being used in the
10:28:03 OR. So -- so FDA can bring to bear, as I did numerous
10:28:08 times over many years and as I trained people to do,
10:28:11 other submissions, literature, expert opinion of -- of
10:28:16 individuals on staff or advisory committee members.
10:28:19 So it's -- it's a very -- it's a more comprehensive
10:28:23 input source than just a submission.
10:28:25 Q. I -- I'm guessing from your comments that
10:28:28 it -- it would be difficult for you to talk about what
10:28:32 happened in terms of the 500 series in terms of its
10:28:35 510(k) clearance process because, according to you, we
10:28:38 don't have the decision-making documentation produced
10:28:42 in this case or available for your review for you to
10:28:46 be able to discuss those matters.
10:28:47 MS. EATON: Object to the form of the
10:28:48 question.
10:28:48 A. Well I can't discuss the reviews without
10:28:50 having them, and having them would shed more light on
10:28:54 FDA's foundation for their finding of substantial

10:28:57 equivalence, but in the absence of that I certainly
10:29:00 understand the review process and what's brought to
10:29:03 bear.
10:29:03 Q. Let me -- let me back up a little bit to --
10:29:06 MR. BANKSTON: In fact, I can just give you
10:29:07 a copy of this really quick. Actually, let's mark
10:29:10 that as an exhibit. And I have a copy for you.
10:29:20 (Ulatowski Exhibit 2 was marked for
10:29:21 identification.)
10:29:21 BY MR. BANKSTON:
10:29:28 Q. Mr. Ulatowski, I handed you what's been
10:29:30 marked as Ulatowski Exhibit 2. It is an attachment to
10:29:34 your report; correct?
10:29:35 A. Yes.
10:29:35 Q. Okay. This is a list of materials that you
10:29:37 reviewed in coming to your opinions in this case.
10:29:40 A. Yes.
10:29:40 Q. Okay. These materials, were these things
10:29:44 that you actually went out and located yourself, or
10:29:49 were they things that were provided to you?
10:29:51 A. Some things I did, some things that were
10:29:55 produced in -- in the litigation.
10:29:55 Q. Okay. One of the things that you'll see in
10:29:57 this list is a long list of Bates-numbered documents;
10:30:01 correct?

10:32:19 Q. Included within that scope of documents you
10:32:23 do not -- you were not provided the decision-making
10:32:26 documents for the 510(k) approval process for the
10:32:29 series 500 Bair Hugger.
10:32:32 A. No. I don't have those. I have no
10:32:36 knowledge if they exist. But those would be obtained
10:32:39 through Freedom of Information requests.
10:32:41 Q. Or perhaps, if they were produced in a
10:32:43 lawsuit, you could also have access to them that way;
10:32:47 right?
10:32:47 A. Well inasmuch as the company has them. But
10:32:50 the company typically doesn't have the FDA review
10:32:52 documents.
10:32:53 Q. Do you know if 3M does?
10:32:54 A. No.
10:32:56 Q. Have you asked them?
10:32:58 Is that a type of material you would have
10:33:01 wanted to review in this case?
10:33:04 A. No. I looked at the 510(k) submissions --
10:33:04 Q. So the decision --
10:33:06 A. -- and -- and -- excuse me -- and in the
10:33:08 510(k)s there's also documentation of FDA's
10:33:10 interaction with the company, the letters that FDA has
10:33:12 written to the company, the responses by the company,
10:33:15 so there's some -- there's important information

document, and what he's asked you to do is provide him the article cited within the document so that he could review that.

MR. BANKSTON: Okay. First of all, that's not an objection. Second of all, I've already said three times put that document over there, I don't want to talk about that document any more.

Q. What we are talking about is what you came to in your report, which is a statement that there is valid scientific evidence of the Bair Hugger's use in operating rooms and that that evidence existed at the time of the Bair Hugger's clearance, and what I think I'm understanding from you is that when I am here today to ask you what evidence that is, what evidence you're relying on to make that opinion, you are telling me today in deposition you will not be able to give me that answer.

A. I'm not prepared to give you that answer --

Q. Okay.

A. -- today.

Q. Thank you, sir.

A. Not to say it does not exist.

Q. Sure. Just not going to disclose that today in the deposition that we are here to talk about.

A. Right.

11:39:37 Q. I'm glad that --

11:39:37 Interesting, because that's exactly where I was going to be going, is that there are other things with the device that can change besides technological characteristics that would require the FDA to ask that question again, is there a possible effect on the safety, and one of those things that could change is the indications for use.

11:39:53 A. Right. It may --

11:39:54 But those are typically very significant changes.

11:39:56 Q. Sure. So, for instance, say you had a device and it had a -- a very significant change in the indications for use. One day it's being used to treat bunions, the next day it's in brain surgery. Right? If you have that kind of significant change, there's going to need to be the question asked does it raise any safety or effectiveness questions.

11:40:13 A. Correct.

11:40:14 Q. If the IFUs are not changed, there's no change in the IFUs, you don't have to ask if there's any changes in safety and effectiveness for the IFUs because those IFUs haven't changed.

11:40:25 A. Correct.

11:40:25 Q. You might have to ask it for other things

11:50:44 to PMA. You have to figure out what kind of device it is. That would be your first step --

11:50:52 A. Well in -- in a very --

11:50:52 THE REPORTER: Just a moment.

THE WITNESS: We're stepping on each other.

11:50:52 THE REPORTER: You are. One at a time, please.

11:50:54 Q. Let's -- let's -- let's do it real simply in little chunks from this doc.

11:50:56 A. I'll slow up as well. Right.

11:51:00 Q. How about this way? Is the product --

11:51:00 The first thing you have to determine is is the product a device.

11:51:02 A. Yes, generally, in a -- in a very general manner.

11:51:05 Q. Now devices can be subject to different FDA regulations.

11:51:08 A. Correct.

11:51:12 Q. One of those regulations is 510(k).

11:51:12 A. Correct.

11:51:15 Q. One --

11:51:16 So then one of the next things you have to determine, is the device subject to 510(k)?

11:51:17 A. Yes. You may --

11:51:18 That may be a front-end decision or will

11:51:22

11:51:24

11:51:26 have to remain as a back-end determination.

11:51:29 Q. Right. Okay. And then one of the next

11:51:32 things you might do when actually looking at the

11:51:34 product -- and I'm not sure what order you might do

11:51:38 this, so if this is out of order, you know, I know --

11:51:39 but one of the steps might be does the product have

11:51:41 the same indication statement.

11:51:44 A. Right.

11:51:45 Q. And in this case you would conclude, no, it

11:51:49 doesn't, and then that would trigger you to ask the

11:51:51 question does that new indication for use present any

11:51:55 safety questions.

11:51:57 A. Yes.

11:51:57 Q. That would be the proper way for a 510(k)

11:52:00 reviewer to go about looking at this product.

11:52:02 A. Yes.

11:52:02 Q. Okay.

11:52:08 MR. BANKSTON: Are we at --

11:52:09 I'm not sure if my time is off of Central or

11:52:12 not. Are we near --

Are we at noon? Is that where we're at, or

11:52:15 are we at 11:00?

11:52:15 (Discussion off the stenographic record.)

11:52:16 (Luncheon recess taken.)

12:55:10 that would have to be answered is do those differences
12:55:13 pose any new questions of safety and effectiveness,
12:55:15 and the answer to that would be no; correct?
12:55:18 A. Well I think we're saying are the
12:55:22 indications different. Well I think there's different
12:55:24 wording, but within FDA's evaluation of devices, FDA
12:55:29 may be more allowing, if I can use that word, in
12:55:37 regard to differences in words or conditions than you
12:55:42 might think. For example, I said is this still used
12:55:47 in hospital? Yes/no. Is this outside of hospital
12:55:50 use? So it depends to what degree and level the FDA
12:55:54 evaluator considered those factors.
12:55:56 Q. Okay. Well let's talk about with this
12:55:58 device, the Bair Hugger, moving from the 200 to the
12:56:01 500. So the 500 was approved, and from what I'm
12:56:05 understanding from you, the FDA understood that there
12:56:08 was a change in indications for use but concluded that
12:56:11 those changes did not affect health and safety
12:56:15 questions.
12:56:16 MS. EATON: Object to the form of the
12:56:16 question.
12:56:17 A. I think that's the case.
12:56:18 Q. Okay.
12:56:35 (Ulatowski Exhibit 4 was marked for
12:56:37 identification.)

12:59:53 interpretation and consider in-hospital use the same
12:59:56 indication use -- for use.
12:59:57 Q. I -- I just want to make sure I'm clear on
12:59:59 your testimony because I was pretty sure you had told
13:00:04 me that from your review of materials in this case and
13:00:04 from your review of materials like what's in front of
13:00:06 you, that the indications statement and the
13:00:08 indications for use on the Bair Hugger fif -- 500
13:00:11 versus the 200 had changed and that that would require
13:00:14 the FDA to ask if that raised new safety of -- safe --
13:00:18 new questions of safety and effectiveness. Do you
13:00:22 agree with that or not?
13:00:22 A. Well I don't think I expressed that in my
13:00:24 report, but as I view this here now, that could be my
13:00:29 approach. But it doesn't mean his approach is
13:00:33 invalid.
13:00:33 Q. And you see where it says "DO DIFFERENCES
13:00:35 ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR
13:00:38 EFFECTIVENESS?" Do you see where it says that?
13:00:40 A. Yes.
13:00:41 Q. That question was not answered; correct?
13:00:43 A. Right. It wouldn't have to be answered.
13:00:45 Q. Right. Because you can skip it if you find
13:00:47 it has the same indications statement.
13:00:49 A. Correct.

13:22:09 Q. Correct. So by your definition, you are not
13:22:13 going to be testifying in this case that there is a
13:22:17 reasonable assurance from a medical point of view that
13:22:18 the device is safe.
13:22:22 A. I don't think I address that in my report
13:22:24 head on.
13:22:25 Q. And I -- uh-huh. And so I just want to
13:22:28 confirm that's not an opinion you're going to be
13:22:31 giving.
13:22:31 A. That's correct.
13:22:31 Q. Okay. I want to talk to you about your
13:22:35 opinion that 3M was appropriate in not considering the
13:22:42 MDR reports that were based on litigation because they
13:22:46 would not reasonably suggest to the company that there
13:22:48 was an event, in basic shorthand. Do you agree that's
13:22:52 essentially your opinion?
13:22:53 MS. EATON: Let me object to the form of the
13:22:54 question.
13:22:55 MR. BANKSTON: What's wrong on that one?
13:22:58 MS. EATON: The word "considering."
13:22:58 MR. BANKSTON: Okay.
13:22:58 MS. EATON: I object to that word. I don't
13:23:00 think it's accurate.
13:23:00 MR. BANKSTON: Okay. Let's -- let's get
13:23:02 that from your report. That's in your report.

14:05:40 involvement in regulating the product line being
14:05:43 litigated.
14:05:48 A. Yes. I've done so before, and I have not
14:05:50 been prevented from doing so upon the opinion of the
14:05:53 Ethics Office. And again, I know it may be a big deal
14:05:59 to you, but this is even -- not even the subject of
14:06:02 this litigation for this particular device.
14:06:04 Q. Well let's -- let's just go ahead and focus
14:06:07 like a laser in on that, then, not just the device but
14:06:10 the issues we're talking about today.
14:06:11 When it comes to the allegations of airborne
14:06:14 contamination, did you have any personal involvement
14:06:15 at all at the FDA to reviewing those allegations?
14:06:19 A. No.
14:06:20 Q. Okay.
14:06:20 A. Well let me take that back. You know, it
14:06:24 was the subject of evaluation of FDA inspection, but I
14:06:29 believe that came along after I had departed from FDA.
14:06:31 Q. What I guess I'm asking you is: Have you
14:06:34 been involved in written communications between, say,
14:06:37 either Augustine or with your current client about
14:06:40 airborne contamination issues while you were
14:06:43 responsible for compliance at the FDA?
14:06:46 A. Airborne compliance --
14:06:48 Airborne contamination generally or

14:12:09 A. -- see what this is all about, because this
14:12:11 is news to me.
14:12:43 Okay, I've read it.
14:12:45 Q. Okay. Your answer?
14:12:46 A. Never saw it before.
14:12:47 Q. That's not the question, sir.
14:12:49 A. What's the question?
14:12:49 Q. The question for the third time is: This is
14:12:51 a letter addressed with your name on it, your address,
14:12:55 that discusses the allegations of airborne
14:12:58 contamination that we've been discussing today.
14:13:00 A. Yes. My address is on here.
14:13:01 Q. Uh-huh.
14:13:02 A. I never received it. I have no knowledge of
14:13:07 it.
14:13:07 Q. You -- well let's -- let's back up. You
14:13:07 don't have any independent knowledge about whether you
14:13:09 actually put hands on this letter seven years ago; do
14:13:12 you?
14:13:12 A. It's unlikely I did because of the reasons I
14:13:14 said already.
14:13:14 Q. All right. Prior to this letter, you had
14:13:18 been directly sent MedWatch reports relating to these
14:13:21 issues; correct?
14:13:22 A. No, I wouldn't have received them directly.

14:22:31 Q. Okay. I want you to flip further into the
14:22:33 discussion of this to page 73.
14:22:35 A. Okay.
14:22:39 Q. All right. I want to direct your attention
14:23:02 to the final paragraph on page 73. Do you see there
14:23:07 it says, "According to the FDA" --
14:23:09 Or let me start that again so -- I want to
14:23:13 make sure we get this word perfect. "According to
14:23:15 FDA, a Warning in labeling may be appropriate if there
14:23:18 is reasonable evidence of an association of a serious
14:23:22 hazard with the use of the device." That's correct?
14:23:26 A. Correct. I reference that.
14:23:28 Q. All right. And that cites your footnote 132
14:23:33 is an FDA guidance document; correct?
14:23:33 A. Correct.
14:23:34 Q. These are known as Blue Book guidance;
14:23:37 correct?
14:23:37 A. Correct.
14:23:38 Q. Okay. And that cites an FDA website;
14:23:41 correct?
14:23:41 A. Correct.
14:23:42 Q. Okay. Now in your report you give four
14:23:45 reasons why a warning -- the lack of a warning was
14:23:49 appropriate, and I want to talk about those four
14:23:51 reasons.

14:28:44 A. Well it's all within the --

14:28:47 Perhaps, perhaps not, because it's all
14:28:49 within the context of the company's risk analysis,
14:28:54 risk management analysis whether or not there's a
14:28:58 credible association of the device to -- to the event.
14:29:06 So if the company has conducted analysis or has
14:29:10 otherwise assessed that and they've decided, no, it
14:29:14 really doesn't apply at this point in time, you know,
14:29:16 we don't have enough data, you know, they may decide
14:29:19 it's not yet time for a warning.

14:29:20 Q. Okay. And that kind of analysis that you're
14:29:23 talking about, that has to be done irrespective of if
14:29:26 there are MDR reports or not.

14:29:28 A. Well the whole -- the --

14:29:30 Right. Well, a device that's not yet
14:29:33 marketed, there is no experience, there are no MDR
14:29:35 reports, so the labeling is based upon those factors I
14:29:38 mentioned before: prior similar devices, literature
14:29:43 related to the device, the risk management analysis
14:29:47 which may lead to labeling of the device. So it's a
14:29:51 number of things.

14:29:51 Q. Okay. I want to go to your second reason
14:29:54 why a warning was not necessarily appropriate in this
14:29:57 case, okay, and that reason is the lack of a direct
14:30:01 causal relationship of infections to forced-air

14:30:04 warming. Do you remember that opinion?
14:30:05 A. Yes. I have it here.
14:30:06 Q. Yeah. And that's right there in front of
14:30:08 you as well.
14:30:09 In other words, nobody's proved a causal
14:30:12 relationship between infection and forced-air warming.
14:30:15 A. To my knowledge, I -- I haven't seen it. I
14:30:18 don't think any of your experts are attesting to that.
14:30:21 Q. Right. And so for that reason, because that
14:30:25 causal relationship has not been proved, warnings are
14:30:29 not necessarily appropriate.
14:30:30 A. Well then that -- that would lend itself to
14:30:34 not having it as a warning. There's other ways of
14:30:37 providing communication, but not necessarily a
14:30:39 warning.
14:30:40 Q. I mean a company is not going to give a
14:30:43 warning for a condition that hasn't been proved.
14:30:45 MS. EATON: Object to the form of the
14:30:46 question.
14:30:46 Q. A causal --
14:30:47 Excuse me. Let me rephrase that. A company
14:30:50 is not going to give a warning regarding a causal
14:30:51 relationship between a condition and a product that
14:30:53 hasn't been proved.
14:30:54 A. Well a warning --

14:33:29 A. Hang on a second.

14:33:37 Yes, --

14:33:38 Q. Okay.

14:33:38 A. -- as I've explained to you.

14:33:39 Q. Yes. So in --

14:33:41 Dr. David, he cited on page 41 of his report
14:33:43 the exact same Blue Books document that you cited.

14:33:46 A. Right.

14:33:47 Q. Okay. And he includes the line that you
14:33:50 omitted, which is a causal relationship need not have
14:33:53 been proved.

14:33:53 A. I just explained that to you.

14:33:55 Q. I'm asking you what's in your report, sir.
14:33:57 That's not in your report; is it?

14:34:00 A. That statement is not in my report.

14:34:01 Q. Right. That statement was omitted.

14:34:04 And these are Blue Book documents that you
14:34:07 relied on and administered for years; correct?

14:34:10 A. Well I don't have a long answer here.
14:34:16 This -- this -- although there's some utility --

14:34:20 First of all, this is a guidance document,
14:34:22 it's not regulation; therefore, it -- it can be
14:34:25 applied to the degree the FDA chooses to apply it and
14:34:29 industry chooses to apply it, because there -- it's
14:34:33 not force of regulation. And secondly, if you read

15:00:47 studies, --
15:00:48 Q. Okay.
15:00:49 A. -- and -- and that's simply the case. I
15:00:52 just, for example, comment on Dr. David's approach to
15:00:58 analyzing the literature indicating that he appeared
15:01:01 to be very selective in what he looked at.
15:01:04 Q. All right. You have -- you have no training
15:01:07 as an orthopedic physician; correct?
15:01:08 A. No.
15:01:09 Q. Okay. You have no training or --
15:01:13 Not an infectious disease doctor; right?
15:01:15 A. I'm not an infectious disease doctor.
15:01:18 Q. All right. One of --
15:01:19 You've got an opinion in your case
15:01:20 addressing Dr. William Jarvis, right, and his
15:01:23 opinions?
15:01:24 A. Related to HICPAC.
15:01:27 Q. Right. Do you feel qualified to address Dr.
15:01:32 Jarvis's opinions as -- his clinical conclusions as an
15:01:32 infectious disease doctor?
15:01:34 A. No.
15:01:34 Q. Okay. You're not an expert in filtration.
15:01:37 A. No, I wouldn't call myself an expert. I
15:01:40 used it in the course of my laboratory work. But no.
15:01:43 Q. You're not an expert in what we would call

16:48:41 A. No.
16:48:41 Q. Okay.
16:48:41 A. No.
16:48:41 Q. For instance, you're not a biomedical
16:48:43 engineer; are you?
16:48:44 A. No. No. My -- my master's degree is in
16:48:47 physiology with an emphasis in biomedical
16:48:51 engineering, --
16:48:51 Q. Okay.
16:48:51 A. -- but it's not an engineering degree.
16:48:53 Q. Now Dr. David, who is a biomedical
16:48:55 engineer, gave an opinion that for each of these
16:48:57 devices, they are most likely safer and as effective
16:49:00 as the Bair Hugger. You aren't going to be giving
16:49:03 opinions to the contrary based on reasonable
16:49:06 engineering certainty; are you?
16:49:08 A. No. But he provides no foundation for his
16:49:11 statement.
16:49:11 Q. I understand you have criticisms. I'm not
16:49:15 asking you that. What I'm asking is a very simple
16:49:18 question, is if you can give me an opinion to a degree
16:49:19 of medical or scientific certainty that these devices
16:49:22 are not safer and as effective than the Bair Hugger.
16:49:28 A. I have -- don't have that in my report.
16:49:30 Q. Okay. You -- you understand what the